

the proximal end of each electrode 66. When the distal end of the electrode 66 penetrating the smooth muscle of the esophageal sphincter 18 or cardia 20 transmits radio frequency energy, the material 70 insulates the mucosal surface of the esophagus 10 or cardia 20 from direct exposure to the radio frequency energy. Thermal damage to the mucosal surface is thereby avoided. The mucosal surface can also be actively cooled during application of radio frequency energy, to further protect the mucosal surface from thermal damage.

In the illustrated embodiment (see Fig. 5), at least one temperature sensor 80 is associated with each electrode. One temperature sensor 80 senses temperature conditions near the exposed distal end of the electrode 66, a second temperature sensor 80 is located on the corresponding spine 58, which rests against the mucosal surface when the balloon structure 72 is inflated.

The system 10 (see Fig. 1) can also include certain auxiliary processing equipment, e.g., an external fluid delivery apparatus 44 for supplying cooling liquid to the targeted tissue, e.g., through holes in the spines, and an external aspirating apparatus 46 for conveying liquid from the targeted tissue site, e.g., through other holes in the spine or elsewhere on the basket 56.

The system 10 also includes a controller 52. The controller 52, which preferably includes a central processing unit (CPU), is linked to the generator 38, the fluid delivery apparatus 44, and the aspirating apparatus 46. Alternatively, the

aspirating apparatus 46 can comprise a conventional vacuum source typically present in a physician's suite, which operates continuously, independent of the controller 52. The controller 52 governs the 5 delivery of processing fluid and, if desired, the removal of aspirated material.

The controller 52 also governs the power levels, cycles, and duration that the radio frequency energy is distributed to the electrodes 10 66, to achieve and maintain power levels appropriate to achieve the desired treatment objectives. The controller 52 can condition the electrodes 66 to operate in a monopolar mode. In this mode, each electrode 66 serves as a transmitter of energy, and 15 an indifferent patch electrode (not shown) serves as a common return for all electrodes 66. Alternatively, the controller 52 can condition the electrodes 66 to operate in a bipolar mode. In this mode, one of the electrodes comprises the 20 transmitter and an other electrode comprises the return for the transmitted energy. The bipolar electrode pairs can be electrodes 66 on adjacent spines, or electrodes 66 spaced more widely apart on different spines.

25 The controller 52 includes an input/output (I/O) device 54. The I/O device 54 allows the physician to input control and processing variables, to enable the controller to generate appropriate command signals. The I/O device 54 also receives 30 real time processing feedback information from the temperature sensors 80, for processing by the controller 52, e.g., to govern the application of

energy and the delivery of processing fluid. The I/O device 54 also includes a graphical user interface (GUI), to graphically present processing information to the physician for viewing or analysis.

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B. Monitoring and Control of Reuse

The handle 28 and the catheter tube 30 form an integrated construction intended for a single use and subsequent disposal as a unit. Alternatively, the handle 28 can comprise a nondisposable component 10 intended for multiple uses. In this arrangement, the catheter tube 30, and components carried at the end of the catheter tube 30 comprise a disposable assembly, which the physician releasably connects to the handle 28 at time of use and disconnects and discards after use. The catheter tube 30 can, for 15 example, include a male plug connector that couples to a female plug receptacle on the handle 28.

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To protect patients from the potential adverse consequences occasioned by multiple use, which include disease transmission, or material stress and instability, or decreased or unpredictable performance, the controller 54 includes a module 48 that controls use of the device 26.

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In the illustrated embodiment (see Fig. 6), the device 26 is supplied as part of a kit 200 that includes, together with the device 26, a usage key card 202. The kit 200 packages the device 26 and usage key card 202 as a unitary, single use item in 30 a sterile fashion within peripherally sealed sheets of plastic film material that are torn or peeled away at the instance of use.

DRAFT - PENDING EXAMINER'S REVIEW